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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,277	10/31/2003	Bryn Hird	8473MR2	2057

27752 7590 02/26/2010

THE PROCTER & GAMBLE COMPANY
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EXAMINER	
WEDDINGTON, KEVIN E	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
02/26/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/699,277	HIRD ET AL.	
	Examiner	Art Unit	
	KEVIN WEDDINGTON	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,8,9,23,25-27 and 29-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,8,9,23,25-27 and 29-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1, 6, 8, 9, 23, 25-27 and 29-38 are presented for examination.

Applicants' amendment and response filed November 12, 2009 have been received and entered.

Accordingly, the rejection made under 35 USC 112, first paragraph (Written Description) as set forth in the previous Office action dated May 14, 2009 at pages 2-4 as applied to claims 25-27 is hereby withdrawn.

Accordingly, the rejection made under 35 USC 112, first paragraph (Scope of Enablement) as set forth in the previous Office action dated May 14, 2009 at pages 4-7 as applied to claim27 is hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 36 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating type II diabetes in a subject with a HIPE foam, does not reasonably provide enablement for preventing type II diabetes in a subject with a HIPE foam. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to a kit comprising a composition comprising an oral administration of a HIPE foam for the prevention of type II diabetes in said subject.

The relative skill of those in the art is generally that of a Ph.D. or M.D.

There are no known preventive therapies for type II diabetes in the art.

It is clear the art to which the present invention relates is highly unpredictable and unreliable with respect to conclusions drawn from laboratory data extrapolated to clinical efficacy.

The breadth of the claims

The claims are very broad and inclusive of any "causes" of type II diabetes.

The amount of direction or guidance provided and the presence or absence of working examples

There are no examples showing the instant composition will, in fact, prevent type II diabetes in a subject not presently at risk of or predisposed to developing such a disease. No examples showing the instant composition is administered to a healthy subject not having type II diabetes, and the administration of the instant composition will prevent the subject from becoming afflicted with type II diabetes during its lifetime. Current modes of treatment are known, but there are no known agents, which can be, prevent the causes of type II diabetes in a healthy subject.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to which cause would be prevented for type II diabetes. The skilled artisan would expect the interaction of a particular drug in the prevention of causes of type II diabetes to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis of the agent. The instant specification sets forth neither such understanding nor any criteria for extrapolating beyond the administration of the composition to treat type II diabetes. Even for the data presented, no direction is provided to prevent specific causes of type II diabetes. Absent reasonable *a priori* expectations of success, one skilled in the art would have to test extensively many conditions that may lead to type II diabetes to discover which cause is prevented. Since each prospective embodiment, as

well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

Claim 36 is not allowed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6, 8 and 9 are again rejected under 35 U.S.C. 102(b) as being anticipated by Bailly et al. (6,030,953), of record, for reason of record as set forth in the previous Office action dated May 14, 2009 at page 7 as applied to claims 1, 3, 6, 8 and 9.

Applicants' remarks regarding the prior art, Bailly et al., does not teach the instant invention are not persuasive since the prior art teaches a composition comprising a polymeric material such as chitosan, combined with a lipase inhibitor (an inhibitor of gastrointestinal lipase), formulated into oral dosage forms for oral administration as powders, tablets, granules, pellets, capsules, suspension (see column 4, lines 31-40). Note Examples 1 (column 5) teaches the instant composition is in the forms of granules and pellets.

If the composition is compressed into tablets, then the chitosan, a polymeric material, is doing the same activity as applicants' instant composition.

The rejection made under 35 USC 102(b) is adhered to.

Claims 1, 6, 8,and 9 are not allowed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 6, 8 and 9 are again rejected under 35 U.S.C. 102(e) as being anticipated by Daggy et al. (6,607,749 B1 with priority filing dated of September 8, 1999), of record, for reason of record as set forth in the previous Office action dated May 14, 2009 at page 8 as applied to claims 1, 3, 6, 8 and 9.

Applicants' remarks regarding the prior art, Daggy et al., does not teach the instant invention are not persuasive since the prior art teaches a composition comprising a polymeric material such as methylcellulose, combined with a lipase inhibitor (an inhibitor of gastrointestinal lipase), formulated into oral dosage forms for

oral administration as powders, tablets, granules, pellets, capsules, suspension (see columns 6 and 7).

If the composition is compressed into tablets, then the celluloses, a polymeric material, is doing the same activity as applicants' instant composition.

The rejection made under 35 USC 102(e) is adhered to.

Claims 1, 6, 8 and 9 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23 and 25-27 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Bailly et al. (6,030,953) or Daggy et al. (6,607,749 B1) in view of Niazi (6,251,421), all of record, for reasons of record as set forth in the previous Office action dated May 14, 2009 at pages 9-10 as applied to claims 23 and 25-27.

Applicants' remarks regarding the prior art (Bailly et al. or Daggy et al.) does not teach the instant composition are not persuasive since each individual prior art reference teaches the polymeric material can be combined with a lipase inhibitor and formulated into tablets, suspensions, and capsules for oral administration. Note the Examiner does not see a difference between the prior art composition for oral dosage forms and the present application composition oral dosage forms wherein polymeric materials are in a tablet or capsule. Does the applicants' tablet produces unexpected results over the prior art's tablets?

Again, to place pharmaceutical compositions into a kit is old and well-known in the art.

The rejection made under 35 USC 103(a) is adhered to.

Claims 23 and 25-27 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 29-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailly et al. (6,030,953) or Daggy et al. (6,607,749) in view of Shiveley et al. (5,817,704) and further in view of Niazi (6,251,421).

Bailly et al. and Daggy et al. were discussed above supra for the combination of a polymeric material and a lipase inhibitor, formulated into oral dosage forms such as

suspension, tablets and capsules for oral administration for sequestering lipophilic material present in the gastrointestinal tract of an animal.

The instant invention differs from the cited references in that the cited references do not teach the glass transition temperature from about -40°C to about 90°C to form the said oral dosage forms. However, the secondary reference, Shiveley et al., teaches that foams intended for applications requiring flexibility should contain at least in continuous region having a T_g as low as possible is well-known in the art.

The instant invention differs from the cited references in that the cited references do not teach the instant composition is used in a kit. However, the tertiary reference, Niazi, teaches that compositions can be in the form of commercial packs containing a lipase inhibitor and instructions for its used in the treatment of obesity or hyperlipidemia (see column 3, lines 39-44).

Claims 29-38 are not allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEVIN WEDDINGTON whose telephone number is (571)272-0587. The examiner can normally be reached on 12:30 pm - 9:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Primary Examiner
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